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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(43)

(PCT Article 36 and Rule 70)

96939612-6

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Applicant's or agent's file reference PF343PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/US96/17957	International filing date (day/month/year) 25 OCTOBER 1996	Priority date (day/month/year) NONE
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant HUMAN GENOME SCIENCES, INC.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

- This report contains indications relating to the following items:

- ☒ Basis of the report
- ☐ Priority
- ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- ☐ Lack of unity of invention
- ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Certain documents cited
- ☒ Certain defects in the international application
- ☒ Certain observations on the international application

RECHERCHE AKTE

Date of submission of the demand 21 MAY 1998	Date of completion of this report 20 DECEMBER 1998
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer GARNETT D. DRAPER Telephone No. (703) 308-0196
Facsimile No. (703) 305-3230	

Form PCT/PEA/409 (cover sheet) (January 1994)*

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I. Basis of the report

1. This report has been drawn on the basis of *Substitute sheets which have been furnished to the receiving Office in response to an indication under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments*;

- ☐ the international application as originally filed.
- ☒ the description, pages (See Attached), as originally filed.
pages _____, filed with the demand.
pages _____, filed with the letter of _____.
pages _____, filed with the letter of _____.
- ☒ the claims, Nos. (See Attached), as originally filed.
Nos. _____, as amended under Article 19.
Nos. _____, filed with the demand.
Nos. _____, filed with the letter of _____.
Nos. _____, filed with the letter of _____.
- ☒ the drawings, sheets/fig (See Attached), as originally filed.
sheets/fig _____, filed with the demand.
sheets/fig _____, filed with the letter of _____.
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE.
- ☒ the claims, Nos. NONE.
- ☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>2-4, 12-16, 18-21</u>	YES
	Claims <u>1, 5-11, 17</u>	NO
Inventive Step (IS)	Claims <u>2-4, 12-16, 18-21</u>	YES
	Claims <u>1, 5-11, 17</u>	NO
Industrial Applicability (IA)	Claims <u>1-21</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 5-11, 17 lack novelty under PCT Article 33(2) as being anticipated, or in the alternative lack an inventive step under PCT Article 33(3) as being obvious over Hillier et al or Myers.

Each of the prior art disclose nucleic acid sequence, which when aligned, shows about 95% similar over portions of the nucleic acid sequence of the Seq ID. Therefore, this art anticipates only those portions of the claims that are directed to portions of the nucleic acid sequence, those portions/fragments/partial domains of the claims; and to hybridizable sequence. Some of the claims define the nucleic acid in terms of an encoded polypeptide or a polypeptide or epitopic portion of the encoded amino acid sequence. Although the prior art does not refer to an encoded amino acid sequence, in view of the fact that the nucleic acids sequence are the same or substantially the same, it would be expected that these sequences would encode for those amino acids regions as recited by the claims. In the event the prior art does not anticipate the claims, then the nucleic acids sequence that are defined in terms of an encoded amino acid sequence would have been obvious from the prior art.

Claims 2-4, 12-16 and 18-21 meet the criteria set out in PCT Article 33(2) and 33(3); and claims 1-21 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed products.

Claims 1-21 meet the criteria set out in PCT Article 33(4) for Industrial Applicability.

NEW CITATIONS

Database EST-STS on MASPAS search, WashU-Merck EST Project (St. Louis, MO, USA) No. R16882, HILLIER ET AL. "y44c01.s2 Homo sapiens cDNA clone 129696 3'", 14 April 1995, see sequence alignment.

Database EST-STS on MASPAS search, Stanford Human Genome Center (SHGC) (Stanford University School of Medicine, Stanford, CA, USA) No. G30081, Myers, Richard. "Human STS SHGC-36171, sequence tagged site"

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 1, 5-10, 12-17, 19-20 are objected to under PCT Rule 56.2(e)(iii) as containing the following defect(s) in the form or contents thereof: The new claims that were submitted 10 January 1997 inserted the phrase "INSERT: DEPOSIT number", but the actual Deposit Numbers were not provided, thus, the claims are incomplete in reference to the Deposit numbers.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to contain an adequate written description of . The description is inadequate because: the description has not taught the meaning of what the percent identity is and how it is determined and what parameters were used. Since different methods are known to produce different results, the description has not provided a written description of such to support the claims.

Claims 1, 5-21 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not adequately described in writing, as required under PCT Rule 5.1(a)(iii), for the reasons set forth in the immediately preceding paragraph.

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because: the description has not enabled the scope of nucleic acids that encode for portions of the amino acid sequence that constitute domains or epitopes. There are not structure/function studies of record to identify regions that are important for structure and function of the protein, or for regions that would be sensitive or tolerant of modification and cleavage for 95% identity or form the various fragments. Further, there are no biological activity assays to ensure that the encoded amino acids will possess the desired activity. In the absence of such, the skilled artisan would be faced with undue experimentation.

Claims 11, 18-21 objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the immediately preceding paragraph.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(6): C12N 15/00, 15/19, 15/11, 15/63, 15/74; C07K 14/52, 16/24; A61K 38/19, 39/395; and US Cl.: 536/23.5, 24.3; 435 /69.5, 70.21, 252.3, 320.1; 530/ 351, 388.23, 389.2; 424/85.1, 141.1

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
pages, 1-89, as originally filed.
pages, NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
numbers, 1-21 as originally filed.
numbers, NONE, as amended under Article 19.
numbers, NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the drawings,
sheets, 1-6 as originally filed.
sheets, NONE, filed with the demand.
and additional amendments:
NONE